

Meeting with Johnson and Johnson: COVID-19 Vaccine discussion

4 September 2020

Present from the NDoH: Anban Pillay, Khadija Jamaloodien, Ruth Lancaster, Marione Schonfeldt, Shereen Govender

Present from Johnson and Johnson: Lynda Arthur, Francisco Plaza, Abeda Williams, Aluwani Museisi

Questions raised by the NDoH:

- What is the price?
- Clinical trials – What is your protocol
- Timelines – when will study finish/analysis/submission to SRA?

[KJ to speak to Pakiso team]

- Will the J&J vaccine be single dose?
- What population groups is this being trialled in (e.g. HIV positive population).
- Where is the manufacturing of the vaccine going to happen, and is there an opportunity for local manufacture? What will be the opportunity for technical transfer to SA manufacturers?
- Is it possible to extend the audit with Deloitte's to all manufacturers, to avoid conflicts of interest?
- What are the special properties of the vaccine? E.g. storage temperatures etc.

Response from J&J:

- Regarding the clinical trial, J&J can send brief overview of the protocol
- J&J are looking at comorbidities. Age group – to confirm. Pregnancy is being excluded from the trial, but want to extend to have broad recruitment of patients.
- Will finish recruitment end Nov. SA is one of multicentre studies. Brazil also a study site. Data expected early Jan. Expected to file with FDA 1st/2nd quarter 2021. Discussion with EMA – employ rapatoir – open filing (not waiting for all data to be data to be available before submit).
- Trying to avoid single dose vial and use multidose. Prob with vials availability.
- Properties of the vaccine - not severe cold chain, not sure of any other particular peculiar properties of the vaccine.
- Local manufacture SA is considered as a site, initial engagement with Biovac as to their capacity and scalability. Biovac would need to do considerable investment and improvement to meet needed volumes. Looking into tech transfer depending on the facility
- Once mapping done by deloitte, will see if can expand on it. J&J involvemnet – happy to have more partners. Interested in using Imperial (which is the J&J distributor). If DOH wants other partners then please advise. Completed the mapping in Kenya, can share this. Deloitte will share the tools (based on WHO guidelines) which need to be adapted to SA context. Assist with data analysis, deloitte will assist. Want to make an app for future reviews/studies.

Regarding COVAX Facility:

Commented [RL1]: Not sure what this word was that Lynda was using

J&J committed to making vaccine available through COVAX. Working hard to this goal, negotiations are still ongoing with the Facility. Once completed, they will ensure SA is aware of this (public announcement will be done). Close to committing an amount to the COVAX facility.

Procurement:

J&J has established a number of bilaterals with different countries. They are open to these two routes (COVAX and bilaterals). They want to know what will happen in future with quantities with countries wanting to explore both pathways, and which countries want one or the other pathway. They want to know what their initial doses quantities will be. Want to know what SA preferential model is. J&J publicly stated that will give 1 billion doses, however they unsure the timing of these dosing being issued, possibly early 2021. On emergency use try to make doses available before official registration. [Lots of connection breaks during this I struggle to hear]

Pricing structure

J&J will make vaccine available on not for profit basis.

They won't be using a tiered pricing structure during the pandemic, it will be one global price. J&J currently working with different institutions (e.g. Bill and Melinda Gates Foundation) to determine what the cost is going to be. Final cost will depend on the ?? (connection break)

If get into a bilateral for the balance out of the COVAX, will the terms differ to that of the COVAX? Price will be independant of procurement process. As long as in the pandemic. Price changes will be based on the bilateral agreement.

Not sure how COVAX will manage the quantities, what their approach will be with outhter countries have with bilaterals?

COVAX indicated that they will use their economies of scale to get a preferential price. But interesting to note J&J will have one flat price irrespective of scale of volumes procured.

J&J: will have similar agreements between bilaterals and COVAX. Terms and conditions will be similar to COVAX.

Equitable distribution – How will J&J decide how much volume will go to different countries and when.

Regulatory of approval – once rapetoire is appointed, will bring in WHO to be part of prequalification. Engaged with SAHPRA to see what their regulatory process will be. When WHO appoints a reviewer with EMA, could SA use (?) to get approval within Africa. There are constraints on companies to register in all countries, they want to provide vaccine to all countries. J&J needs to understand SAHPRA processes. DOH will have to be an applicant for the process (ok reception dying here again)

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Does SA Want to pursue COVAX or a bilateral with J&J. Anban – NdoH still investigating best approach. No formal decision has been made in any direction as yet. Trying to keep the conversation open at the moment. The opportunity through COVAX may be limited by volume which may be

topped up through bilaterals. Haven't formally defined the priority population, although internationally recognised that the HCWs would have first choice. Thereafter possibly the elderly and the highest mortality comorbidity groups. We still need to quantify these population groups. All dependant on the performance of the vaccine however.

Private sector – nothing formalised but usually the medical schemes active in the vaccine space. May differ in COVID. Not keen to have a 2 tier in supply and procurement due to issues with equity. Want to have one country system for access to the vaccine, and then engage with private on how to coordinate distribution in-country based on guidelines that are yet to be developed on access.

J&J thinks that the distribution in-country should be done by the doh and that bilaterals should be done with DOH, not keen to have different agreements with different groups in the country.

Distribution is not included in the J&J price.

Anban requests for regular catchup with J&J to keep the conversation open. Need to keep eye open on when the vaccine will be available. There are a lot of other issues to be considered, such as the cold chain. This is the first of this kind of vaccine purchasing in the country and will involve a lot of work.

Will share this info with the MAC-VACCines to inform them where J&J stands.

J&J suggest MAC – see overall presentation from the J&J to have a more clinical and education ppt on the vaccine. Can link in the international team.

Anban – Will discuss with MAC if they keen to engage directly with companies.

Questions – send to Aluwani Museisi as the focal person who will coordinate responses.

Meeting ended 12:02.